

**iPLEDGE PROGRAM  
FREQUENTLY ASKED QUESTIONS**

**A. TECHNICAL ASSISTANCE**

**B. PRESCRIBER**

**C. ALL USERS**

## **A. TECHNICAL**

### **What are the steps for first-time login to iPLEDGE?**

*Once registered, you will receive your username and password in the mail. Upon first login to iPLEDGE you will be asked to select a personal 4-digit numeric password and select a date of personal significance. The selection of a personal password is a security feature that ensures password confidentiality. A date of personal significance is collected by the system as confidential data that will be asked of you for identity authentication purposes should you require assistance from a Call Center operator during your participation in the iPLEDGE program. The date of personal significance can be any memorable date such as your birth date or wedding date.*

*If you are logging into iPLEDGE via phone or web for the first time you will enter your Username and Password from the user form that was mailed to you [Please see “**How can I login using my telephone?**” or “**How can I login using the web?**”]. Immediately after you have successfully logged in the system will ask you to select your personal password. You will be asked to enter the old (original) password from your user form and then you will enter a new 4-digit number of your choice. You will use the new password you have just chosen to login again in the future. To continue, you will be asked for your new password, then you will be asked to enter your date of personal significance twice. If you are using the telephone system you will enter the date in a mmddyyyy format. If you are using the iPLEDGE website you will enter the date in a mm/dd/yyyy format using the forward slash key. Upon successful entry of the date of personal significance the system will proceed to your main menu of options and you may begin performing functions in the iPLEDGE system.*

### **How can I login using the web? How do I handle Internet browser issues?**

*To use the iPLEDGE web functionalities it is required that you use Internet Explorer 6.0 or greater. If you do not have this Internet browser, you can download it at [www.microsoft.com](http://www.microsoft.com). To login to iPLEDGE go to [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and locate the Login section in the middle of the screen. Type your username and password into the appropriate boxes. For example, if your username is ABC123, type exactly ABC123 in the Username box. If your password is 1234, type 1234 in the Password box. Click on the green “Login” button and your homepage with all appropriate functions will appear. If you are experiencing browser issues, your browser (i.e. Mozilla Firefox) may be blocking the iPLEDGE site. You can resolve this by 1) Disabling the pop-up blocker completely every time you need to use the site, or 2) adding [www.ipledgeprogram.com](http://www.ipledgeprogram.com) into your browser’s list of allowed sites. If this does not resolve the issue, it is recommended that you use Internet Explorer 6.0.*

### **What should I do if I become locked out of iPLEDGE?**

*If you make three unsuccessful attempts to login to iPLEDGE, a security feature that locks your account is deployed. Your account will automatically unlock after 30 minutes or you can speak with an iPLEDGE customer service representative to have it unlocked. Call the iPLEDGE Program at 1-866-495-0654 and listen for the option to speak to a representative.*

### **How can I login using my telephone?**

*To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system first asks for your iPLEDGE user ID followed by the pound sign. Enter each digit of your user ID/username followed by the \* key on your telephone touchpad. Then press the # key at the end of your username. Refer to the table below.*

To Enter	Press	To Enter	Press	To Enter	Press	To Enter	Press
2	2*	A	22*	J	55*	S	77777*
3	3*	B	222*	K	555*	T	88*
4	4*	C	2222*	L	5555*	U	888*
5	5*	D	33*	M	66*	V	8888*
6	6*	E	333*	N	666*	W	99*
7	7*	F	3333*	O	6666*	X	999*
8	8*	G	44*	P	77*	Y	9999*
9	9*	H	444*	Q	777*	Z	99999*
0	0*	I	4444*	R	7777*	1	1*

*For example, if your username is 12345, type 1\*2\*3\*4\*5\*# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 222\*555\*1\*2\*3\*4\*5\*#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no \* or # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.*

### **How are iPLEDGE patient numbers assigned?**

*Once a Prescriber performs the “Activation” step in iPLEDGE, a shipment of patient educational kits is sent to the Prescriber’s address via UPS. The shipment includes two yellow kits (binders) for female patients of childbearing potential and two green kits (binders) for male patients or female patients who cannot get pregnant. Inside each kit is a tab labeled “Patient Identification Card”. In this section you will find a patient ID card attached, which can be peeled off and given to the patient along with the kit. In the upper right corner of the card appears a 10-digit patient number, which is the patient ID number you will enter when registering the patient. For each new patient you must have a new patient educational kit available to assign to the patient.*

### **How can I order additional program materials?**

*To order additional program materials prescribers must first login to iPLEDGE via telephone or web. If you are accessing the system by telephone you must login and then choose option 4, “To hear options on requesting program information.” The system will guide you through the ordering options. If you are accessing the system by web you must login and then click on “Order Materials” from the options listed down the left side of the screen. The system will display the options so you can place your order. The materials you order should be delivered to you within 7 to 10 business days from the order date.*

### **Why is the “Confirm Counseling” button not available for my patient on the web?**

*iPLEDGE enforces the requirements of the program, which include allowing only one prescription per patient per month. If your patient is not eligible for the next monthly visit according to the program timelines, the “Confirm Counseling” activity cannot be performed for that patient and the button will be grayed out. Once the appropriate number of days elapses from the previous counseling date, the system will allow you to enter the next counseling date.*

## **B. PRESCRIBERS**

### **Please explain the registration process.**

*Registration and activation is a two-step process.*

Registration - Prescribers may obtain a registration form on-line from the website's homepage or by calling 1-866-495-0654 and requesting to have a pre-filled registration form faxed to the office. They are instructed to complete and fax the signed form to the iPLEDGE program 1-866-495-0660. If a prescriber fills out the application form on-line they will still need to print it and fax or mail the signed form to iPLEDGE. The program requires a signed registration form received by iPLEDGE for each prescriber that requests to enroll in the program.

Mailing 1 - Once registered, the prescriber will receive a mailing which includes the prescriber's iPLEDGE Program username (which is your DEA# or a system generated number), the prescriber's iPLEDGE password, instructions for prescriber activation, instructions for office designee registration, the prescriber guide, among other iPLEDGE Program related-materials.

Activation - You will need your username and password to activate. You may activate via either the web site, [www.ipledgeprogram.com](http://www.ipledgeprogram.com), or automated phone system, 1-866-495-0654. For ease of use, it is recommended that you activate on the website. The system will present a list of attestation points that you must agree to in order to complete your activation. This is a quick procedure that the prescriber must perform. The activation expires in one year from the date of activation. A prescriber only needs to activate once a year. There is no need to register every year.

Mailing 2 - Once activated, the prescriber will receive a second mailing, which includes four patient's kits. Two kits are for females who can get pregnant and two kits are for males and females who cannot get pregnant. If the prescriber requires additional patient kits you may order these via the web site at [www.ipledgeprogram.com](http://www.ipledgeprogram.com) or automated phone system, 1-866-495-0654.

### **What is the difference between a Delegate and a Designee?**

Delegate – another physician/prescriber

A prescriber can delegate another registered and activated iPLEDGE prescriber to cover for him/her during a scheduled absence (travel, vacation, etc.). This also can be used to delegate to another registered and activated prescriber in a multiple doctor practice where a patient may see any of the doctors in the office.

Designee – an office staff designee, a staff member in the prescriber's office

After the prescriber has registered and activated with iPLEDGE the office staff associated with the prescriber will be able to register as well. Each office staff designee will receive his/her own username and password. A prescriber may have one or more designated office staff. Prescribers must designate office staff separately. A registered designee may perform all patient functions on behalf of the prescriber. An office designee may support all the registered prescribers in a multi-physician practice and will also have rights for any patient delegated to a delegate prescriber. Each office staff designee will only need to register once, even if they support several prescribers. Also, if a prescriber is not activated in the iPLEDGE system, neither the prescriber nor the designated office staff can register a patient. The prescriber is responsible for any actions of all designees under him/her.

## **How does an Office Staff Designee register and become affiliated to a Prescriber?**

*Registration and affiliation is a two-step process.*

**Registration** - To register an Office Staff Designee, the **Prescriber** must login to the iPLEDGE website and click on “Register New Designee” from the options listed down the left side of the screen. The **Prescriber** must then complete the fields on the registration form, click on “Save and Print” at the bottom of the page, and sign the printout. The signed form must then be faxed to the number that appears on the form. ***(Please note that iPLEDGE will no longer accept hand-written forms created using the blank forms that were provided in the program binders).*** Upon processing of the signed form, the Designee’s Username and Password is sent via US Mail.

**Affiliation** - Upon receipt of the Username and Password, the Designee must arrange with the Prescriber to affiliate the Designee to the Prescriber. To do this the Prescriber must login to the iPLEDGE website and click on “Manage Designees” from the options listed down the left side of the screen. The Prescriber must then enter the Designee’s username into the Designee Username box and click on the “Add” button. The Designee’s name will then appear on the “Your Designees” list and the Designee may begin to perform functions on behalf of the Prescriber. If the office does not have access to the iPLEDGE website, the prescriber can call 1-866-495-0654 to be assisted with Designee registration.

**Please show the iPLEDGE program requirements with respect to days: 30-days, 23-days, and 7-days.**

### **Female of Child Bearing Potential (FCBP)**

#### **Initial 30 Days**

*Day 1 = Patient Registration and entry of screening pregnancy result. Screening pregnancy test can occur up to 30 days prior to patient registration. Screening pregnancy test may be conducted in the prescriber’s office.*

*30 Days – Patient must be on two forms of contraception for 30 days after patient registration.*

#### **First Month**

*As early as Day 31 = Once the patient has been on contraception for 30 days, the patient is eligible for the office visit and the prescriber has the ability to confirm counseling.*

#### **Day 1**

- *The Confirmation Counseling Date. (The counseling is done on this office visit.) This date starts the 7-day window. You can backdate this date, however, the system only will take dates after the previous 30-day waiting period has ended.*

#### **Days 1 to 7**

- *The second pregnancy test must occur within 7 days after counseling and during the first 5 days of the patient’s menstrual cycle. This, and all subsequent monthly pregnancy tests, must be conducted at a CLIA certified laboratory.*
- *The patient must answer questions in the system to demonstrate her comprehension of the iPLEDGE requirements.*
- *The prescriber must enter the pregnancy results. The pregnancy results can be entered on the “Enter Pregnancy Test Results” screen.*
- *The patient can fill the prescription if all program requirements are met.*

#### **Days 8 to 30**

- *The 23- day waiting period (whether a patient filled the prescription or not).*

***Each Subsequent Month (Through End of Therapy)***

*As early as Day 31, Resets to Day 1*

*Day 1*

- *The Confirmation Counseling Date. (The counseling is done on this office visit.) This date starts the next 7-day window. You can backdate this date, however, the system only will take dates after the previous 23-day waiting period has ended.*

*Days 1 to 7*

- *The next pregnancy test must occur within 7 days after counseling.*
- *The patient must answer questions in the system to demonstrate her comprehension of the iPLEDGE requirements.*
- *The prescriber must enter the pregnancy results.*
- *The patient can fill the prescription if all program requirements are met.*

*Days 8 to 30*

- *The 23- day waiting period (whether a patient filled the prescription or not).*

***After Therapy***

*Continue using two forms of contraception for 30 days after therapy*

*Immediately (Day 1 or 2)*

- *The follow up pregnancy test must occur.*

*Day 30*

- *The final pregnancy test must occur 30 days post therapy.*

***NON-FCBP and MALES***

***Initial 30 Days***

*Day 1 = Patient Registration and eligible for the office visit and the prescriber has the ability to confirm counseling. There is no 30-day waiting period requirement.*

*Day 1*

- *The Confirmation Counseling Date. This date starts the 7-day window. You can backdate this date, however, the system only will take dates on or after the date of registration.*

*Days 1 to 7*

- *The patient can fill the prescription.*

*Day 8 to 30*

- *The 23- day waiting period (whether a patient filled the prescription or not).*

***Each Subsequent Month (Through End of Therapy)***

*As early as Day 31, Resets to Day 1*

*Day 1*

- *The Confirmation Counseling Date. This date starts the next 7-day window. You can backdate this date, however, the system only will take dates after the previous 23-day waiting period has ended.*

*Days 1 to 7*

- *The patient can fill the prescription.*

*Days 8 to 30*

- *The 23- day waiting period (whether a patient filled the prescription or not).*

***After Therapy***

- *There are no requirements post therapy.*

**Do males or females of non-child bearing potential have to wait 30 days to start isotretinoin, answer questions each month, and use contraception for the iPLEDGE program?**

*No, once the male or female of non-childbearing potential patient is registered, the prescriber can start the 7-day window by going to the “manage patients” screen and confirming patient counseling. Males and females of non-childbearing potential do not have to answer questions each month in the iPLEDGE system, only females of child bearing potential need to do so. Males and females of non-childbearing potential do not need to use contraception to qualify for the iPLEDGE program.*

**Can pregnancy tests be conducted prior to the prescriber office visit?**

*No, the pregnancy test cannot be done prior to the prescriber office visit. For female patients of childbearing potential, the initial screening pregnancy test (1<sup>st</sup> test) must be conducted on the date of registration or no more than 30 days prior to patient registration. For ongoing monthly pregnancy tests, the specimen must be collected in a CLIA certified laboratory and the results must be entered on or within 7 days after the office visit.*

*(see Package Insert for timing requirements).*

**Does a female of non-child bearing potential need to take pregnancy tests?**

*No, only females of child bearing potential need to take pregnancy tests and answer monthly questions.*

**How long does the patient need to wait between monthly pregnancy tests?**

*The patient can take their next pregnancy test 23 days after the end of their last 7-day window and within 7-days after the next office visit (after the prescriber has confirmed them in the system).*

**Does a female of childbearing potential need to be on birth control or another form of contraception if she chooses abstinence? Or, is abstinence an acceptable option for iPLEDGE?**

*The program requirement for an FCBP is to be on two effective forms of birth control unless you choose to be abstinent. A patient choosing abstinence does not need to choose another form of birth control. Abstinence means an FCBP will not have sex or sexual contact with any male 24 hours a day, 7 days a week. This could be hard to do especially if the patient is use to having sex. It is easier not to have sex when it is a lifestyle choice, such as a religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence). Abstinence is not a recommended way to prevent pregnancy for the iPLEDGE Program.*

**What are acceptable primary forms of birth control?**

*FCBP patients must use two forms of effective birth control together correctly all the time (of which one must be a Primary form):*

- *For at least one month before starting isotretinoin*
- *While taking isotretinoin – treatment usually lasts four to five months*
- *For one month after the last dose of isotretinoin – for continued protection against pregnancy*

*Effective forms of contraception include both primary and secondary forms of contraception:*

<b>Primary Forms</b>	<b>Secondary Forms</b>
<ul style="list-style-type: none"><li>• <i>Tying my tubes (tubal sterilization)</i></li><li>• <i>Partner’s vasectomy</i></li><li>• <i>Intrauterine device</i></li><li>• <i>Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)</i></li></ul>	<i>Barrier forms (always used with spermicide):</i> <ul style="list-style-type: none"><li>• <i>Male latex condom</i></li><li>• <i>Diaphragm</i></li><li>• <i>Cervical cap</i></li></ul> <i>Others:</i> <ul style="list-style-type: none"><li>• <i>Vaginal sponge (contains spermicide)</i></li></ul>

**What forms of birth control are NOT acceptable for the iPLEDGE Program?**

*You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.*

- Birth control pills without estrogen (progesterone-only mini-pills)
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield

**What if the primary forms of contraception are contraindicated for the patient?**

*The patient should discuss this issue with her gynecologist.*

**Please explain the data entry requirements for contraception.**

*The primary method of contraception entered into the system by the prescriber and patient must match each month. Advise patients that if they have incorrectly entered their contraceptive method and they receive a message, from the system, “to contact their prescriber,” the patient can go back into the system and re-enter the correct information regarding their contraceptive method.*

**How many attempts do patients have to demonstrate comprehension?**

*If an FCBP answers her questions incorrectly, she will be given an opportunity to answer another question on the same topic. If she gets this wrong, she will be directed to review the appropriate educational materials. She can, at a later time, login again and attempt to answer the questions correctly.*

**The patient just filled their isotretinoin prescription, how much time do we need to wait before the patient fills their next prescription?**

*The patient can visit their prescriber’s office to begin the qualification process for another prescription as early as 23 days after the end of their last 7-day window. It is 30 days from the recorded counseling date / office visit date.*

**Does a new FCBP patient starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?**

*Yes. The 30-day waiting period is required of all FCBPs taking isotretinoin. There are no exceptions.*

**How do I enter the pregnancy test results using Serum test versus urine tests?**

*Serum test results must be entered using the specific lab value. The iPLEDGE system will not accept a range as the value. We recommend contacting the CLIA certified lab to obtain the specific lab value. Urine test results must be entered as positive or negative.*

**Can I backdate?**

*Yes, you may backdate a counseling date or pregnancy test specimen collection date. For male patients and female patients of non-childbearing potential, the counseling date must be on or after the patient's date of registration (for the first month) or after the 23-day waiting period (for subsequent months). For female patients of childbearing potential, the counseling date must be after the 30-day waiting period (for the first month) or after the 23-day waiting period (for subsequent months). Additionally, the counseling date will be day 1 of the 7-day window. If a counseling date of more than 7 days in the past is entered, the patient will not be able to fill the prescription, as the 7-day window will have already passed. The pregnancy test specimen collection date must be on or after day 1 of the 7-day window to be considered as the mandatory monthly pregnancy test for an FCBP patient.*



*For example:*

*An office visit occurred on March 1. The next office visit occurred on March 31. Data can be entered on April 1 for the visit that occurred on March 31, but not for a visit that occurred on March 30 (because this is inside the 30 day window).*

**I do not understand why when I enter the patient's pregnancy test results, the system generates a message that says "this patient's status has not changed?"**

*You can always enter pregnancy test results in the iPLEDGE system. This is to allow reporting of a pregnancy at any time. However, to qualify for a prescription, the patient must have a pregnancy test conducted and the result is entered on or within 7 days after the office visit. The patient's status will not change if the patient is waiting the initial 30 days to start treatment or the 23 days between 7-day windows.*

**May I fax or phone in prescriptions to the pharmacy?**

*Yes, prescribers may fax or phone in isotretinoin prescriptions to the pharmacy.*

**Where do I find a list of local pharmacies that participate with the iPLEDGE program?**

*Registered patients can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature after they login to the website. At this time it is only accessible under the patient section of the system.*

**Low-dose maintenance therapy for patients?**

*All patients receiving isotretinoin, regardless of the dose prescribed, are required to have monthly office visits and new prescriptions written. No refills are permitted. For FCBP, monthly pregnancy tests, must be conducted throughout treatment regardless of dose or duration. There are no exceptions. All patients receiving isotretinoin therapy must adhere to the requirements of the iPLEDGE program.*

**Who needs to answer patient monthly comprehension questions?**

*Female patients of childbearing potential must answer education questions to demonstrate their comprehension on a monthly basis by logging into the system (either by calling the automated telephone system at 1-866-495-0654 or accessing the website at [www.ipledgeprogram.com](http://www.ipledgeprogram.com)). Males and female patients of non-childbearing potential (FNCBP) do not need to answer the monthly comprehension questions.*

**Can I download consent forms from [www.ipledgeprogram.com](http://www.ipledgeprogram.com)?**

*At this time, downloading consent forms from the web is not an option. Consent forms are included in the patient education materials along with their User ID. Because the patient kit is important for the patient to have, consent forms and user IDs are not provided via [www.ipledgeprogram.com](http://www.ipledgeprogram.com).*

**What if my office is excluded from HIPAA requirements?**

*HIPAA is still under discussion. Prescribers can refer to a medical specialty society for support on becoming HIPAA compliant.*

## C. ALL USERS

**If a patient's 7-day prescription authorization window expires before they arrive at the pharmacy to fill the prescription, is there any way to override the system?**

*No. A lapse in treatment would result when a registered patient does not pick up the isotretinoin prescription within seven days after the office visit, the office visit being day 1. This may result in a patient missing isotretinoin treatment for no less than 23 days. Patients should make every effort possible to complete the iPLEDGE program requirements and pick up the prescription within the 7-day window to avoid a lapse in isotretinoin treatment.*

**Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?**

*At this time, there is no test database. Please refrain from entering dummy data in the iPLEDGE system as that could negatively impact patient data that is reported to the FDA.*

**How can I download iPLEDGE materials?**

*Users can download the iPLEDGE materials from the website using version Acrobat 7.0. The link to this free Acrobat download is available on any page that has materials available for download.*

**Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?**

*Residency is not a requirement of the program as long as patients see a doctor in the U.S. and fill their prescription in the U.S. However, a U.S. mailing address must be provided.*

**Will the manufacturers reinstate veterinary use of isotretinoin?**

*Isotretinoin is for human consumption only. At this time, there are no plans to include animals in the iPLEDGE program.*

**Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?**

*Hospital pharmacies must follow all the requirements of the iPLEDGE program and cannot process partial isotretinoin prescriptions (or break blister packs). All pharmacies need to dispense a 30-day supply of isotretinoin because the iPLEDGE system will allow one prescription authorization a month.*